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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,098	09/20/2001	Yukio Toyoda	46342/56000	9857

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EXAMINER

SCHLAPKOHL, WALTER

ART UNIT	PAPER NUMBER
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1636

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08/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/869,098	Applicant(s) TOYODA ET AL.	
	Examiner Walter Schlapkohl	Art Unit 1636	<i>WLF</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8, 11 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 11 and 17 is/are allowed.
- 6) ☒ Claim(s) 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of the papers filed 5/8/2007 in which claim 1 was cancelled and claims 5-6, 8, 11 and 17 were amended. Claims 5-8, 11 and 17 are pending and under examination in the instant Office action.

Any rejection of record not recited herein is hereby
WITHDRAWN.

Specification

A substitute specification excluding the claims is required pursuant to 37 CFR 1.125(a) because the specification appears to be a literal translation of a foreign language document, and is not in the proper English vernacular.

A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive

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characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Surwit et al (WO 98/31396, of record). This is a new rejection (i.e., reinstated) not necessitated by Applicant's amendment.

Applicant's invention is drawn to a recombinant vector comprising DNA which comprises a human UCP-2 promoter region which consists of all or part of the base sequence consisting of nucleotides 1 to 2270 of SEQ ID NO: 1, wherein the part of the

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base sequence may consist of nucleotides 255 to 430 of SEQ ID NO:1, nucleotides 255 to 727 of SEQ ID NO:1, nucleotides 717 to 1133 of SEQ ID NO:1 or nucleotides 1133 to 1389 of SEQ ID NO:1 (claim 5). Applicant's invention is further drawn to said recombinant vector which further comprises a DNA comprising a base sequence encoding a reporter molecule under the control of the UCP-2 promoter region (claim 6) as well as a transformant transformed by the recombinant vector described in claim 5 (claim 7).

The Surwit et al application teaches the identification and cloning of nucleic acid sequences encoding human uncoupling protein 2 (hUCP-2), 5' sequences controlling the expression of hUCP-2 expression, as well as methods of using the regulator sequences to identify modulators of hUCP-2 expression. For example, Surwit et al teach the identification of a human BAC clone comprising approximately 20 kb of human sequence which the practitioners believe comprises the entire gene and entire promoter (hUCP2.BAC deposited with the ATCC; e.g. see page 16-17). Further, Surwit et al teach the isolation of a lambda EMBL3 phage comprising ~14 kb of human sequences. This clone comprises all 8 exons of the human UCP-2 gene, as well as a minimum of 3 kb of DNA upstream of the putative +1 site (e.g. page 32). The UCP coding sequence downstream to the 5' flanking

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sequence can be considered a "base sequence encoding a reporter molecule" (claim 6).

Given the size of the genomic clones obtained by the inventors of the Surwit et al application (e.g. at least 3 kb upstream of the transcription initiation site) and the fact that the sequences recited in the claims are all within ~2.2 kb of the initiation site (e.g. see amended Figure 4 of the instant specification), it is reasonable to expect that the clones obtained by Surwit et al necessarily comprise SEQ ID NO: 1 and the recited fragments thereof.

On October 7, 2005, Applicant provided an alignment of the the UCP-2 5' region disclosed by Surwit et al and Applicant's SEQ ID NO:1. This alignment shows that the portion of Applicant's SEQ ID NO:1 comprising nucleotides 1733-2837 are at variance with portions of the 5' flanking region of the UCP-2 gene disclosed by Surwit et al. However, this alignment does not show any variance in four of the claimed "parts" of the bases sequence of SEQ ID NO:1 encompassed by Applicant's claim 5. Specifically, the part of the base sequence consisting of nucleotides 255 to 430 of SEQ ID NO:1, nucleotides 255 to 717 of SEQ ID NO:1, nucleotides 717 to 1133 of SEQ ID NO:1 and nucleotides 1133 to 1389 of SEQ ID NO:1 have not been distinguished over that of Surwit et al. Because the Office

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does not have the facilities for examining and comparing the Applicant's product with the products of the prior art, the burden is on the Applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product, i.e. the lambda EMBL3 phage comprising a minimum of 3 kb of DNA upstream of the putative +1 site does not comprise nucleotides 244-430, nucleotides 255-717, nucleotides 717-1133 and/or nucleotides 1133-1389 of Applicant's SEQ ID NO:1). See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

It is further noted that MPEP 2111.03 instructs that in situations wherein open language (such as Applicant's "DNA which comprises a human uncoupling protein-2 (UCP-2) promoter region") and "closed" language (such as Applicant's "which consists of all or a part of the base sequence consisting of nucleotides 1 to 2270 of SEQ ID NO:1") are used together, the open language controls:

In re Crish, 393 F.3d 1253, 73 USPQ2d 1364 (Fed. Cir. 2004) (The claims at issue "related to purified DNA molecules having promoter activity for the human involucrin gene (hINV)." *Id.*, 73 USPQ2d at 1365. In determining the scope of applicant's claims directed to "a purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1 wherein said portion

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consists of the nucleotide sequence from ... to 2473 of SEQ ID NO:1, and wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity," the court stated that the use of "consists" in the body of the claims did not limit the open-ended "comprising" language in the claims (emphases added). Id. At 1257, 73 USPQ2d at 1367. The court held that the claimed promoter sequence designated as SEQ ID NO:1 was obtained by sequencing the same prior art plasmid and was therefore anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. Id. at 1256 and 1259, 73 USPQ2d at 1366 and 1369. The court affirmed the Board's interpretation that the transition phrase "consists" did not limit the claims to only the recited numbered nucleotide sequences of SEQ ID NO:1 and that "the transition language comprising" allowed the claims to cover the entire involucrin gene plus other portions of the plasmid, as long as the gene contained the specific portions of SEQ ID NO:1 recited by the claim[s]" Id. at 1256, 73 USPQ2d at 1366.

Therefore, Surwit et al anticipates claims 5-7.

Allowable Subject Matter

Claims 8, 11 and 17 are allowed.

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy

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should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571)

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272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Joseph Woitach can be reached at (571) 272-0739.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

July 30, 2007


DAVID GUZO
PRIMARY EXAMINER